

PATENTS**UNITED STATES PATENT AND TRADEMARK OFFICE**

Application:	10/667,685	Examiner:	Anuradha Ramana
Confirmation:	9399	Art Unit:	3733
Filed:	September 22, 2003	Atty Ref.:	DEP0777USNP
Inventor:	Heldreth		
Title:	MODIFIED SYSTEM AND METHOD FOR INTRAOPERATIVE TENSION ASSESSMENT DURING JOINT ARTHROPLASTY		

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February 27, 2009
(Date of Deposit)
Stephen J. Manich
(Name of applicant, assignee, or Registered Representative)
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(Signature)
February 27, 2009
(Date of Signature)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicants request review of the last rejection in the above-identified application. No
amendments are being filed with this request. This request is being filed with a notice of appeal.
The review is requested for the reasons stated on the attached sheets.

Respectfully submitted,
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Dated: February 27, 2009

ARGUMENTS IN SUPPORT FOR PRE-APPEAL BRIEF REVIEW

This is the first request for pre-appeal review for this application. Applicants are seeking a pre-appeal review to avoid the time and expense associated with a full appeal.

I. Introduction

In general terms, the presently claimed invention relates to a system for balancing soft tissue during total joint arthroplasty through use of two trials: an instrumented trial for one of the bones and a trial that is not instrumented for the other bone. The instrumented trial includes a flexible sensor array and a protector. Complementary mounting members associated with the protector and the first trial may temporarily secure the sensor array between the protector and the first trial (claim 1). Alternatively, the protector may have a clam-shell type structure, with the sensor array sandwiched between portions of the protector (claims 2 and 16). A stud may extend between the protector the first trial for temporarily fixing the position of at least part of the protector with respect to the trial (claim 10). Positive locating features may be provided so that the sensor array is positively located with respect to at least one of the protector and the first trial (claim 12).

All of the independent claims in this case are written in Jepson format. The preambles of these claims describe elements of the system that are claimed in another pending application: U.S. Pat. App. Ser. No. 10/667,763, entitled “Apparatus, System and Method for Intraoperative Performance Analysis During Joint Arthroplasty”¹. Central to this appeal is the question of whether the elements recited in the preambles of the independent claims in the present case constitute limitations. If they do, then the rejections based upon 35 USC §102(b) are in error. Another issue involved in this appeal is whether the Examiner has applied the correct standard under 35 USC §112, second paragraph, to claims 2 and 16. The final issue is whether the Examiner has established a *prima facie* case of obviousness under 35 USC §103.

II. Claims on Pre-Appeal Review

Five independent claims are currently pending: claims 1, 2, 10, 12 and 16. For the purposes of this pre-appeal review, the Applicants request the panel focus only on four of the independent claims: 1, 2, 12 and 16.² Of these four independent claims, claims 1 and 12 were rejected as being unpatentable under 35 U.S.C. §102 as being anticipated by Hershberger et al.

¹ U.S. Pat. App. Ser. No. 10/667,763 was rejected on 12-19-2008.

² While the dependent claims add further limitations that further patentably distinguish over the prior art, the errors with respect to the independent claims are so fundamental that if corrected should by bring all claims into allowance.

(U.S. Pat. 5,470,354). The other two independent claims (2 and 16) were rejected as being indefinite under 35 USC §112, second paragraph.

III. Argument

Pending in this case is a Final Office Action dated 09/02/2008.

A. Rejections under 35 USC §102 (claims 1 and 12)

In the final rejection, the Examiner failed to refer to portions of the preambles of claims 1 and 12. In particular:

Claim 1 defines the contours of the first joint trial as follows: “the curved contours of the articulating surface of the first joint trial and the curved contoured surfaces of the protector being curved *in a plurality of intersecting cross-sections....*” The final rejection does not refer to curvature in a plurality of intersecting cross-sections for the articulating surface of the first joint trial. Moreover, the element (84) the Examiner has identified as the first joint trial in Hershberger et al. is flat and planar on its upper and lower surfaces; these surfaces are not curved in a plurality of intersecting cross-sections. Accordingly, a rejection under 35 USC §102 is improper.

Claim 12 defines the contours of the first joint trial and the protector as follows: “the curved contour of the articulating surface of the first joint trial and the curved contoured surfaces of the protector being curved *in a plurality of intersecting cross-sections....*” As in the case of claim 1, the final rejection does not refer to curvature in a plurality of intersecting cross-sections for the articulating surface of the first joint trial and the element (84) the Examiner has identified as the first joint trial in Hershberger et al. is flat and planar on its upper and lower surfaces and these surfaces are not curved in a plurality of intersecting cross-sections. Accordingly, a rejection under 35 USC §102 is improper.

In the Final Rejection, the Examiner indicated that “Applicant’s arguments are not directed to claim limitations.” The Examiner further wrote: “The Examiner reiterates that if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention’s limitations, then the preamble is not considered a limitation and is of no significance to claim construction.”

However, the Federal Circuit has made clear that “the preamble is a limitation in a Jepson-type claim.” *Epcon Gas Sys. Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 61 U.S.P.Q.2D 1470 (Fed. Cir. 2002). **Accordingly, the Examiner erred in failing to consider the above quoted recitations from the preambles of claims 1 and 12 in applying the standard under 35 USC §102.**

B. Rejections under 35 USC §112 (claims 2 and 16)

In the final rejection, the Examiner applied the incorrect legal standard under 35 USC §112, second paragraph. The Examiner wrote: “it is unclear how the second portion of the protector overlies the first portion when the system is in an assembled configuration.”

As the Federal Circuit wrote in *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004), “The requirement to ‘distinctly’ claim means that *the claim must have a meaning discernible to one of ordinary skill* in the art when construed according to correct principles...*Only when a claim remains insolubly ambiguous without a discernible meaning* after all reasonable attempts at construction must a court declare it indefinite.”

In the case of claim 2, the claim recites that the protector element “comprises a first portion and a second portion joined along an axis, and wherein the first portion of the protector overlies at least a part of the curved contour of the articulating surface of the first trial and the second portion overlies at least a substantial part of the sensor array and at least a substantial part of the first portion of the protector.” Thus, the claim clearly encompasses a clam-shell type of structure for the protector, with the sensor array sandwiched between the two portions of the protector, as shown for example in FIG. 12. The Examiner has not stated that one of ordinary skill in the art would be unable to discern the meaning of the claim. And it is difficult to conceive how one of ordinary skill in the art would fail to understand that the claim encompasses a structure where the second portion of the protector overlies the first portion when the system is in an assembled state. Consider a box with a hinged lid set on a table and an object in the box: two portions of the box (the body and the lid) are joined along an axis (the hinge); at least one portion of the box overlies the table; and when closed, the second portion of the box (the lid) overlies the object in the box and at least part of the other portion (the body) of the box. One of ordinary skill in the art would understand this structure and relationship and would be able to discern the meaning of claim 2.

Claim 16 similarly calls for the protector to have “a first portion and a second portion joined along an axis, wherein the first portion of the protector overlies at least part of the curved contour of the articulating surface of the first trial and the second portion overlies at least a substantial part of the sensor array and a substantial part of the first portion of the protector.” The above argument with respect to claim 2 applied equally to claim 16. One of ordinary skill in the art would be able to discern the meaning of claim 16.

C. Rejections under 35 USC §103 (claims 28-37)

The Examiner failed to establish a *prima facie* case of obviousness of claims 28-37.

In the first embodiment of Hershberger et al., the sensor component 150 is disclosed as being located on the planar upper surface 92 of the base member 84 of the tibial component. (See Col. 6, lines 53-60). This location is illustrated in FIGS. 5 and 7. Hershberger et al. teaches that “[t]he surfaces are flat and smooth in order to provide a satisfactory surface for the force transducer to contact.” (col. 6, lines 59-60). This is contrary to the teachings of the claimed invention, wherein curved, contoured elements are nested together.

V. Conclusion

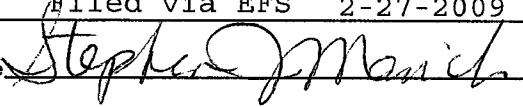
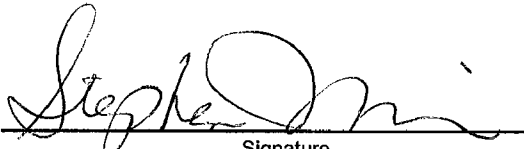
Applicants request the panel to find claims 1-4, 12-17 and 28-37 allowable.

Filed: 27-Feb-2009

Respectfully submitted,

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>Filed via EFS 2-27-2009</u> Signature <u></u> Typed or printed name <u>Stephen J. Manich</u>		Application Number <u>10/667,685</u>	Filed <u>09/22/2003</u>
		First Named Inventor <u>Heldreth</u>	
		Art Unit <u>3733</u>	Examiner <u>Anuradha Ramana</u>
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>			
I am the		 Signature	
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<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)			
<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>30,657</u>		<u>574-372-7796</u> Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		<u>February 27, 2009</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

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